Hardian Health

Innovate UK

Health Innovation Network South London

Timelines & costs for regulatory processes

When should developers start considering regulation, how long does it take and cost if all processes are followed?

Outline

Timelines and Costs

This talk will cover:

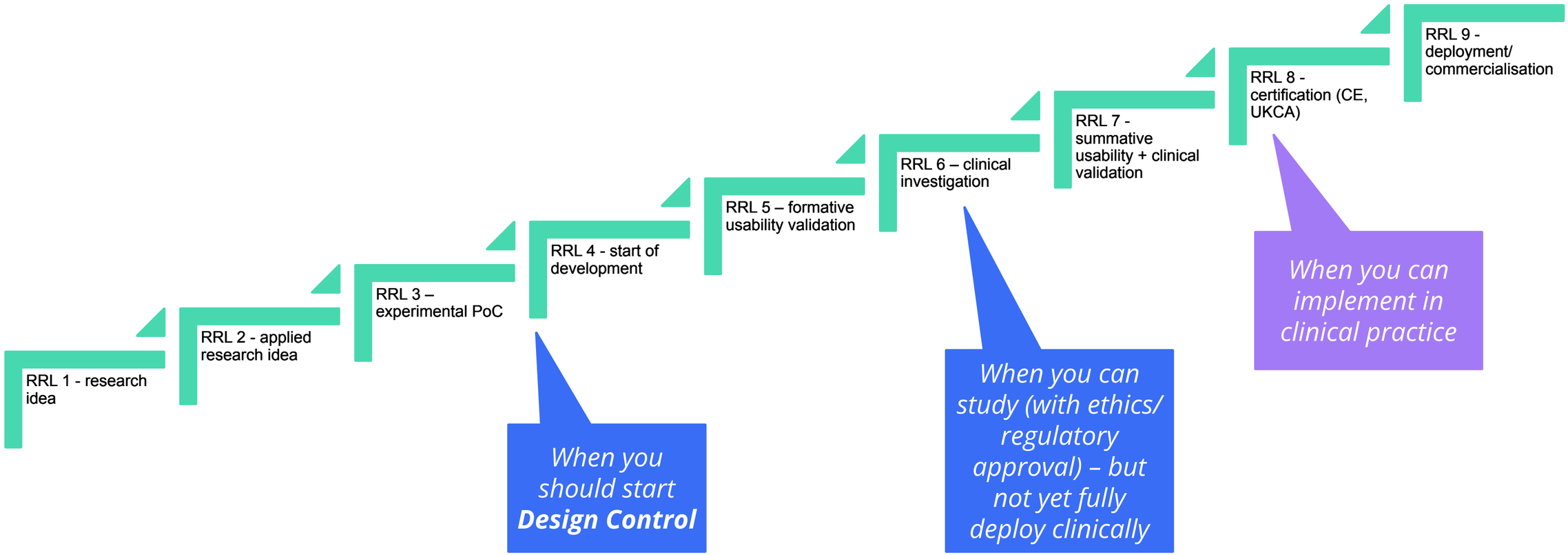
- When to start regulatory processes
- QMS set up and costs
- Technical File creation and costs
- Registration and notification fees
- Staff & training

Timelines

When should you start your regulatory strategy?

- As soon as you have a concept or idea for a medical purpose, that is the best time to consider your regulatory strategy.
- It is far easier, cheaper and quicker to consider regulatory compliance early than to ignore it until the last minute. ‘Regulatory debt’ is expensive! Non-compliance can be fatal to a business.
- Your first device certification takes the longest and is the most expensive since you need to start from scratch. Each subsequent one becomes faster and cheaper.

Regulatory readiness levels



QMS Timelines

A QMS should be built and not bought

Instilling a **culture of quality** into a company takes time, it doesn't happen overnight just by purchasing a quality management system or templates.

Quality assurance is an **ongoing process** covering the lifetime of your device. Everyone in your company is responsible for ensuring quality - not just the quality manager!

Typically we recommend around 3 months to design a QMS, 3 months to deploy and train everyone, and 3 months to actually use it before an audit = up to **9 months**.

QMS Costs

A QMS should be built and not bought

ISO standards - you need to purchase copies of relevant standards. We recommend having a subscription to take advantage of up to a 50% discount ~ £1500 annually.

QMS - build a bespoke QMS in-house using Atlassian/Jira/Github/Google docs for around £12-16K (or you can choose to purchase an eQMS system costing up to £30K annually).

Training - it is always cheaper to train internal team members to conduct internal audits rather than pay external auditors - training courses are around £2-4K pp.

QMS Costs

A QMS should be built and not bought

Staff - we highly recommend hiring a quality manager as early as possible - estimated annual FTE cost £70-100K.

Certification - you should get ISO13485 certified by an accredited EU/UK body (ideally the same body that will audit your technical file for CE/UKCA) - costs range depending on company size and revenues - around £16K for small startups

Recertification - every three years you must be re-certified - budget around £5K

QMS Costs

A QMS should be built and not bought

Total first year - from scratch to certified ISO13485 QMS ~ £35-45K

Ongoing ~£1.5K in updating standards annually

Re-certification ~ £5K every three years

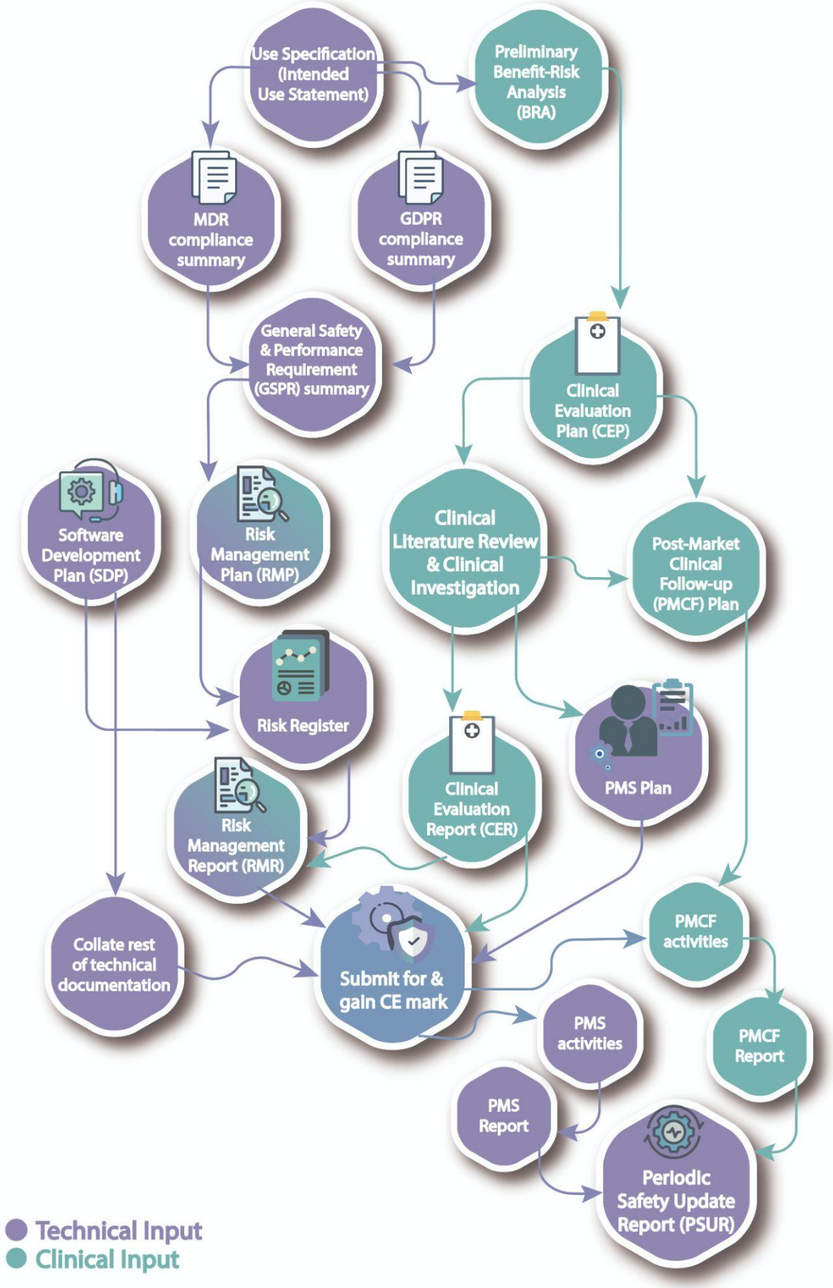
TF Timelines

How long it takes to build a technical file

The Technical File is how you document all processes and evidence while designing, building, deploying and maintaining your medical device.

The TF contains both technical and clinical documentation. It is always better to document as you go along, rather than scramble to do it all retrospectively.

Many documents and processes are ‘live’, and can be performed in parallel as you set up your QMS.


Use Specification (Intended Use Statement)
Preliminary Benefit-Risk Analysis (BRA)
MDR compliance summary
GDPR compliance summary
General Safety & Performance Requirement (GSPR) summary
Clinical Evaluation Plan (CEP)
Software Development Plan (SDP)
Risk Management Plan (RMP)
Clinical Literature Review & Clinical Investigation
Post-Market Clinical Follow-up (PMCF) Plan
Risk Register
PMS Plan
Clinical Evaluation Report (CER)
Risk Management Report (RMR)
Collate rest of technical documentation
Submit for & gain CE mark
PMCF activities
PMS activities
PMCF Report
PMS Report
Periodic Safety Update Report (PSUR)
Technical Input
Clinical Input

TF Timelines

How long it takes to build a technical file

Technical documentation - assuming a functional QMS, you will need to conduct full risk analysis, software lifecycle development plan etc - typically takes 2-4 months

Clinical documentation - systematic literature review ~ 2 weeks, Clinical Evaluation Plan ~ 1 month, conducting a Clinical Investigation ~ 3-6 months, writing it all up into a Clinical Evaluation Report ~ 1 month.

Many documents and processes are ‘live’, and can be performed in parallel.

Accreditation Timelines

How long it takes to receive certification

There is a LONG queue for Approved/Notified Bodies - current quotes are between 12-18 months - so book your audit date well in advance!

2 stage audit - takes place over a couple of weeks. You will receive feedback within a month and be given a further month or so to respond to any non-conformities before a third stage audit.

Proper planning can align your technical file creation to be done while in the queue for an audit, however, to apply for an audit you will need some skeleton documentation first.

Accreditation costs

Getting your UKCA / CE mark

2-stage CE mark audit - prices range depending on notified body, device class and company size, but typically ~£25K. You can expect to pay more for an expedited review.

Unannounced audit fees - at least once every five years ~£5K

Many documents and processes are ‘live’, and can be performed in parallel as you set up your QMS.

Registration and notification fees

Putting your device on market

Clinical Investigation - MHRA must be notified in order to conduct an investigation of non-regulated marked devices - Class I, IIa, or IIb = £7,472

Non-EU manufacturer deploying in EU: annual fee for EU Authorised Representative (approx. €2000)

Person Responsible for Regulatory Compliance (PRRC) - if no-one is qualified in-house, then fees for an external appointment range from £1-2K per year per device.

Staff & training

Staff - we highly recommend hiring a quality manager as early as possible - estimated annual FTE cost £70-100K.

Training - it is always cheaper to train internal team members to conduct internal audits rather than pay external auditors - training courses are around £2-4K pp.

Consultants - external experts can be brought in to assist, but do not expect them to do all the work for you - you must “learn to drive your own car”!

Adding it all up

Total costs for one three year cycle for one device

QMS - £40-60K

(6-9 months to set up, deploy, train and get certified)

Technical File - costs for 2-3 FTE staff, or 1 FTE staff and external consultants ~ £150K

Accreditation and registration fees ~ £60K

(12-18 months solely based on backlog of Notified Bodies)

Ongoing costs - EUAR, PRRC, staff training ~£10K per year

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